REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 48-69 are in the case.

I. ELECTION/RESTRICTION

The election of Group I is hereby affirmed. Claims 60, 61 and 69 are withdrawn from further consideration.

II. SAME INVENTION DOUBLE PATENTING

Claims 48-53 and 62 stand provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 22, 24, 26 and 28-30 and 14 of copending Application Serial No. 09/930,494. The rejection is respectfully traversed.

In response, and without conceding to the merit of this rejection, the claims of the present application have been amended, without prejudice, to remove reference to prevention of the recited condition. Withdrawal of the same invention double patenting rejection is now believed to be in order. Such action is respectfully requested.

III. OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 54-59 stand provisionally rejected on obviousness-type double patenting grounds as allegedly unpatentable over claims 31, 32 and 38-41 of copending Application Serial No. 09/930,494. Applicants will consider filing a Terminal Disclaimer when otherwise allowable subject matter is indicated.

IV. CLAIM OBJECTIONS

Claims 48, 56 and 62 stand objected to in view of abbreviations allegedly appearing in the those claims. In response, it is not seen how objection arises with respect to claim 62. Claims 48 and 56 have been amended to meet the objection. Basis appears at page 21 and at page 27, second paragraph. Withdrawal of the objections is now respectfully requested.

V. THE 35 U.S.C. §112, FIRST PARAGRAPH, REJECTION

Claims 48-59 and 62-68 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the treatment of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction, allegedly does not reasonably provide enablement for the prevention of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction.

In order to advance prosecution, and without conceding to the merit of the rejection, the claims have been amended to remove reference to prevention of the recited condition. Withdrawal of the 35 USC 112, first paragraph, rejection is accordingly respectfully requested.

VI. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION

Claims 48-59 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for the reasons stated on page 7 of the Action. The Examiner asserts that the phrase "a pyrimidine nucleotide precursor" renders all claims in which that language appears indefinite. The Examiner asserts that, in the absence of distinct chemical core, distinct language to describe the structural modifications, or the chemical names of precursor compounds of this invention, the identity of the precursors would be difficult to describe. The Examiner further asserts that the metes and bounds of the precursor compounds applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. The rejection is respectfully traversed.

In response, the phrase "a pyrimidine nucleotide precursor" is not indefinite. The term is defined at page 7, and numerous examples are provided. Based on this disclosure, and the level of ordinary skill in this art, the reader would have no difficulty in understanding the phrase "a pyrimidine nucleotide precursor" as used in the present claims. Withdrawal of the 35 USC 112, second paragraph, rejection is accordingly respectfully requested.

VII. THE OBVIOUSNESS REJECTION

Claims 48-59 and 62-68 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Page et al in combination with U.S. 6,316,426 to von Borstel et al. That rejection is respectfully traversed.

Page describes the use of uridine to treat patients with a rare disease associated with excess activity of the enzyme 5'-nucleotidase, an enzyme involved in degradation of nucleotides. In scientific publications describing these patients (*see*: Page, et al., Adv. Exp. Med. Biol. 1998; 431:789-92 and Page et al., Adv. Exp. Med. Biol. 1991;309B:345-8, copies attached), there is no indication or suggestion of evidence for mitochondrial respiratory chain dysfunction as a molecular basis for 5'-nucleotidase excess. Applicants submit that the finding by Page that nucleotide precursors (uridine or ribose) are clinically useful in treating a disorder in which the only known molecular deficit is an excess of an enzyme (5'-nucleotidase) involved in nucleotide degradation, would **not** have led one of ordinary skill to suspect that uridine or ribose would be useful in treating conditions caused by mitochondrial respiratory chain dysfunction, even those which might manifest some similar symptoms. As noted above, patients with this condition are rare, and there are no clear implications for other diseases.

The above-noted deficiencies of Page are not cured by the '426 U.S. patent to von Borstel. The '426 U.S. patent discloses that acylated ribonucleoside derivatives are effective in treating a number of disorders that involve functional impairments in tissue and organ systems involving metabolic deficiencies. Therefore, even if Page and von Borstel would be combined to treat 5'-nucleotidase excess, one still would not have arrived at the claimed invention of treating pathophysiological consequences of mitochondrial respiratory chain dysfunction. Accordingly, no *prima facie* case of obviousness is established in this case. Withdrawal of the obviousness rejection is respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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Attachments: Ferrante, et al., 2000; Du, et al., 2001; Page et al. (1991), Page et al (1998); Ravina, et al., 2003; PTO 1449 IDS fee